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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,719	03/29/2001	Kathleen A. Donovan	07039-260001	4609

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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

15

DATE MAILED: 05/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

15

Interview Summary

Application No.

09/821,719

Applicant(s)

DONOVAN ET AL.

Examiner

Myron G. Hill

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All participants (applicant, applicant's representative, PTO personnel):

(1) Myron G. Hill.

(3) Ronald Lundquist.

(2) James Housel.

(4) _____.

Date of Interview: 09 May 2003.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
If Yes, brief description: _____.

Claim(s) discussed: All of record.

Identification of prior art discussed: All of record.

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: The Office hereby withdraws the finality of the last Office Action, paper #14. Applicant will amend the claims to clarify the proccess for quantitating IL-1 beta based on the measurement of IL-6.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.


Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.


Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

DETAILED ACTION

The Group and/or Art Unit of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Hill.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1- 10, and 15 (with response claims 1- 5, 7- 10, and 15 plus new claim 28, claim 6 was canceled) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that 17- 22 and 23- 27 are each broken into 5 groups and all drawn to inhibitors of IL-1 beta and it would not be a burden to search. This is not found persuasive because these are drawn to different methods than elected group I and the search for the method of group I is not coextensive for the search for the other methods.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11- 14, and 16- 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1- 5, 7, 15, and 28 are being treated on the merits (see claim objections below).

Claim Objections

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Claims 5, 8, and 10 are objected to under 37 CFR 1.75(c), as being of improper dependent form. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims depend from themselves. The claims will be treated in this office action as if: claim 5 depends from claim 4 and claim 10 depends from claim 9, and for claims 8 and 10, see the following paragraph.

Claims 8, 9, and 10 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is not clear what the basis of the correlation is between IL-1 beta and IL-6 is and it is not clear what the conclusion of the method is. The term "elevated" in claims 3 and 4 is a relative term that renders the claim indefinite. The term "elevated" is not defined by the claim, the specification does not provide a standard for

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ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what level is to give a likelihood that correlates with "indicative of" or "likely to progress" to disease state. In claims 3, 4, and 7 what is the metes and bounds of the certainty of the diagnosis or determining the likelihood of progression to disease? Are there false positives or false negatives? In claim 15 is not clear what the "known standard or a patient determined standard" is and the method is not complete because there is no conclusion that indicates what monitoring the status indicates or what causes the change in status.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Carter (1990 British Journal of Haematology 74: 424- 431, in IDS).

Carter teaches that there is dose dependent correlation between IL-1 beta and the amount of IL-6 produced (figure 1 and page 430, second full paragraph). Carter also teaches that myeloma cells cultured with stromal cells produced IL-6 and this IL-6 production could be blocked by addition of anti IL-1 beta antibodies (Table III).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7, 15, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carter and Klein (1989 Blood Vol 73, No 2, pages 517- 526).

Carter teaches that there is dose dependent correlation between IL-1 beta and the amount of IL-6 produced (figure 1 and page 430, second full paragraph). Carter also teaches that myeloma cells cultured with stromal cells produced IL-6 and this IL-6 production could be blocked by addition of anti IL-1 beta antibodies (Table III).

Carter does not teach correlation of IL-6 to disease state.

Klein teaches that "bone marrows from patients inactive/slightly active myeloma could be distinguished from those patients with fulminating disease on the basis of IL-6 levels" (page 519 column 2) and shows the measurement of IL-6 of individuals in different disease states in Figure 1.

It would have been obvious to one skilled in the art would have been motivated to measure the level of IL-6 in a myeloma cell- stromal cell co-culture of Carter to determine the status of an individual or monitor the status of an individual as shown by Klein. One skilled in the art would have been able to assay for the amount of cytokine in

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a sample and determine the status of a patient or monitor the status of a patient for change.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art to assay a culture and determine the amount of cytokine produced to monitor or assay for a disease state with a reasonable expectation of success.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill
Patent Examiner
May 8, 2003